

SUMMARY OF SAFETY AND EFFECTIVENESS

The *Bipolar Suction Coagulator (Angled)* is a disposable device, designed to be used in soft tissue surgical procedures that require slow to rapid fluid evacuation and low energy output for the coagulation of the tissue i.e., neurosurgery, endoscopic, sinusoidal, ENT, OB-GYN and plastic surgery.

Biological safety has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. The materials have been tested in accordance with ISO Standard 10993-1, Biological Evaluation of Medical Devices, Part 1 (external communicating device, blood path indirect, contact duration category "A").

Sterilization safety has been assured to a sterility assurance level (SAL) of 10^{-6} . Sterility has been validated in accordance with and complies with the requirements of the applicable sections of the following standards:

100% Ethylene Oxide (EtO) sterilization: AAMI Guideline for Industrial EtO Sterilization of Medical Devices (ST27- 1988).

The *Bipolar Suction Coagulator (Angled)* has been performance tested in accordance with and complies with the requirements of the applicable sections of the following standards:

IEC 601-1-2 (1988), Medical Electrical Equipment Part 1; General Requirements for the Safety.

IEC 601-2-2 (1991), Medical Electrical Equipment Part 2; Particular Requirements for the Safety of High Frequency Surgical Equipment.

ANSI/AAMI HF 18 (1993), Electrosurgical Devices

The *Bipolar Suction Coagulator (Angled)* is substantially equivalent in function and intended use to the Bipolar Suction Coagulator, 510(k) K960455.